IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH, LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
WATSON LABORATORIES, INC., ACTAVIS, INC., AND ACTAVIS PHARMA, INC.,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Alcon Research, Ltd. ("Alcon"), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of defendants' submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of ILEVRO® (nepafenac ophthalmic suspension) 0.3% ("ILEVRO") prior to the expiration of U.S. Patent Nos. 7,947,295 ("the '295 patent") and 8,921,337 ("the '337 patent").

2. By letter dated January 19, 2016 (the "Notice Letter"), Watson Laboratories, Inc. ("Watson Laboratories") notified Alcon that Watson Laboratories had submitted to the FDA an ANDA, No. 208816, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic nepafenac ophthalmic suspension, 0.3% ("Watson's ANDA Product") prior to the expiration of the '295 and '337 patents. Upon

information and belief, Watson's ANDA Product is a drug product that is a generic version of ILEVRO, containing the same or equivalent ingredients in the same or equivalent amounts.

PARTIES

3. Plaintiff Alcon Research, Ltd. is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

4. Upon information and belief, defendant Watson Laboratories is a corporation organized and existing under the laws of the State of Nevada having a place of business at 311 Bonnie Circle, Corona, California 92880, and a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Watson Laboratories is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market, and in the course of doing do, relies on contributions from Actavis, Inc. and Actavis Pharma, Inc. Upon information and belief, Watson Laboratories is a wholly owned subsidiary of Actavis, Inc.

5. Upon information and belief, defendant Actavis, Inc. ("Actavis"), formerly known as Watson Pharmaceuticals, Inc., is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market through various operating subsidiaries.

6. Upon information and belief, defendant Actavis Pharma, Inc. ("Actavis Pharma"), formerly known as Watson Pharma, Inc., is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at Morris

Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis Pharma is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market, and in the course of doing so, relies on contributions from Watson Laboratories and Actavis. Upon information and belief, Actavis Pharma is a wholly owned subsidiary of Actavis.

7. Upon information and belief, Watson Laboratories, Actavis, and Actavis Pharma operate as an integrated, unitary generic pharmaceutical business. Upon information and belief, Watson Laboratories, Actavis, and/or Actavis Pharma share common employees, officers, and directors. Upon information and belief, Watson Laboratories, Actavis Pharma, and Actavis are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Watson's ANDA Product, and enter into agreements with each other that are closer than arm's length. Upon information and belief, Actavis and Actavis Pharma participated in, assisted, and cooperated with Watson Laboratories in the acts complained of herein. Except where otherwise noted, Watson Laboratories, Actavis Pharma, and Actavis are referred to collectively herein as "Watson."

8. Upon information and belief, and consistent with their practice with respect to other generic products, Watson Laboratories, Actavis, and Actavis Pharma participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 208816, the ANDA at issue in this litigation. For instance, by letter dated January 19, 2016, Watson Laboratories directed Alcon to send any written notice regarding confidential access concerning ANDA No. 208816 to Brian Anderson, Esq., Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. Upon information and belief, Mr. Anderson is Vice

President, Intellectual Property – Global Generics at Actavis. Upon information and belief, Actavis directed Watson Laboratories to submit ANDA No. 208816.

9. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 208816, Actavis, Watson Laboratories, and Actavis Pharma will act in concert to distribute and sell Watson's ANDA Product throughout the United States and within Delaware.

JURISDICTION AND VENUE

10. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391, 1400(b), 2201, and 2202.

11. This Court has personal jurisdiction over Watson Laboratories, Actavis, and Actavis Pharma.

12. Watson Laboratories is subject to personal jurisdiction in Delaware because, among other things, Watson Laboratories has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Watson Laboratories develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Alcon's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. Upon information and belief, Watson Laboratories earns revenue from the distribution in Delaware by Actavis Pharma of generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson Laboratories is the named applicant on approved ANDAs. Upon information and belief, Actavis and/or Watson Laboratories are parties to one or more contractual agreements regarding the distribution of such generic

pharmaceutical products. Upon information and belief, such agreements are at less than arm's length. Upon information and belief, various products for which Watson Laboratories is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

13. Actavis is subject to personal jurisdiction in Delaware because, among other things, Actavis, itself and through its wholly-owned subsidiaries Watson Laboratories and Actavis Pharma, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Actavis, itself and through its wholly-owned subsidiaries Watson Laboratories and Actavis Pharma, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. Upon information and belief, Actavis has consolidated its activities and financial results in its most recent SEC filings and Annual Report with, among other subsidiaries, Watson Laboratories and Actavis Pharma. Upon information and belief, Actavis earns revenue from the distribution in Delaware by Actavis Pharma of generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson Laboratories is the named applicant on approved ANDAs.

14. Actavis Pharma is subject to personal jurisdiction in Delaware because, among other things, Actavis Pharma has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Actavis Pharma, acting as the agent of Actavis and Watson Laboratories, distributes and sells in Delaware and elsewhere in the United States generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson

Laboratories is the named applicant on approved ANDAs. Upon information and belief, Actavis Pharma and/or Watson Laboratories are parties to one or more contractual agreements regarding the distribution of such generic pharmaceutical products. Upon information and belief, such agreements are at less than arm's length. In addition, Actavis Pharma is subject to personal jurisdiction in Delaware because, upon information and belief, Actavis Pharma is incorporated in Delaware and has appointed a registered agent in Delaware for service of process. Upon information and belief, Actavis Pharma is registered, under 24 Del. C. § 2540, to distribute Watson's generic pharmaceutical products in Delaware and holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy.

15. In addition, upon information and belief, Watson's ANDA No. 208816 seeks FDA approval to sell Watson's ANDA product throughout the United States, including in Delaware, prior to the expiration of the '295 and '337 patents, and thus seeks FDA approval to engage in conduct that will infringe Alcon's patent rights throughout the United States, including in Delaware. Moreover, upon information and belief, Watson knowingly used the process contemplated by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), to challenge Alcon's patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Watson has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

16. Upon information and belief, Watson, with knowledge of the Hatch-Waxman Act process, directed the Notice Letter to Alcon Research, Ltd., an entity incorporated in Delaware, and alleged in the Notice Letter that Alcon's patents are invalid. Upon information and belief, Watson knowingly and deliberately challenged Alcon's patent rights, and knew when it did so that it was triggering a forty-five day period for Alcon to bring an action for patent infringement under the Hatch-Waxman Act.

17. Because Alcon Research, Ltd. is a corporation incorporated in Delaware, Alcon suffers injury and consequences from Watson's filing of ANDA No. 208816, which challenges Alcon's patent rights, in Delaware. Upon information and belief, Watson knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. Watson has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending the Notice Letter to Alcon, a Delaware corporation, that it would be sued in Delaware for patent infringement.

18. In addition, this Court has personal jurisdiction over Watson because Watson Laboratories, Actavis, and Actavis Pharma regularly engage in patent litigation concerning FDA-approved branded drug products in this District and do not contest personal jurisdiction in this district. *See, e.g., Takeda Pharma. U.S.A., Inc. v. Watson Labs., Inc.*, C.A. No. 14-268 (Watson Laboratories and Actavis); *Fresenius Kabi USA, LLC v. Watson Labs, Inc.*, C.A. No. 14-161 (Watson Laboratories and Actavis); *Sanofi v. Watson Labs, Inc.*, C.A. No. 14-265 (Watson Laboratories); *Depomed, Inc. v. Watson Laboratories, Inc. – Florida*, C.A. No. 13-342 (Actavis and Actavis Pharma (as Watson Pharma, Inc.)). In addition, Watson has affirmatively sought transfer of patent litigation concerning FDA-approved branded drug

products to this District. *See* Mot. to Transfer, *Bayer Pharma AG v. Watson Labs., Inc.*, C.A. Nos. 14-01804, 14-02065 (D.N.J. Apr. 17, 2014) (Watson Laboratories, Actavis, and Actavis Pharma).

19. Watson Laboratories, Actavis, and Actavis Pharma have also purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., Takeda Pharma. U.S.A., Inc. v. Watson Labs., Inc.*, C.A. No. 14-268 (Watson Laboratories); *Fresenius Kabi USA, LLC v. Watson Labs, Inc.*, C.A. No. 14-161 (Watson Laboratories); *Kissei Pharma Co. v. Hetero USA Inc.*, C.A. No. 13-1091 (Actavis); *Kissei Pharma Co. v. Sandoz Inc.*, C.A. No. 13-1092 (Actavis); *Novartis Pharma Corp. v. Actavis, Inc.*, C.A. No. 13-371 (Watson Laboratories, Actavis, and Actavis Pharma (as Watson Pharma, Inc.)).

20. Upon information and belief, if ANDA No. 208816 is approved, Watson will manufacture, market, and/or sell Watson's ANDA Product within the United States, including in Delaware, consistent with Watson's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Watson regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Watson's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware.

21. Upon information and belief, if ANDA No. 208816 is approved, Watson will directly or indirectly market and distribute Watson's ANDA Product in Delaware. Upon information and belief, Watson's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware.

Each of these activities would have a substantial effect within Delaware and would constitute infringement of Alcon's patent in the event that Watson's ANDA Product is approved before the patent expires.

22. Upon information and belief, Watson derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Watson and/or for which Watson Laboratories is the named applicant on approved ANDAs. Upon information and belief, various products for which Watson Laboratories is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

23. For the above reasons, it would not be unfair or unreasonable for Watson Laboratories, Actavis, and Actavis Pharma to litigate this action in this District, and there is personal jurisdiction over Watson Laboratories, Actavis, and Actavis Pharma here.

BACKGROUND

24. ILEVRO is an ophthalmic suspension for topical administration to the eye. The active ingredient in ILEVRO is nepafenac. ILEVRO is indicated for the treatment of pain and inflammation associated with cataract surgery.

25. The '295 patent, entitled "Ophthalmic Compositions Containing a Synergistic Combination of Two Polymers," was duly and legally issued on May 4, 2011. Alcon Research, Ltd. is the assignee of and owns the '295 patent. A true and correct copy of the '295 patent is attached hereto as Exhibit A.

26. The '337 patent, entitled "Carboxyvinyl Polymer-Containing Nanoparticle Suspensions," was duly and legally issued on December 30, 2014. Alcon Research, Ltd. is the

assignee of and owns the ’337 patent. A true and correct copy of the ’337 patent is attached hereto as Exhibit B.

27. The ’295 patent and ’337 patent have each been listed in connection with ILEVRO in the publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, maintained by the FDA, commonly known as the “Orange Book.”

28. The purpose of Watson’s submission of ANDA No. 208816 was to obtain approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of Watson’s ANDA Product prior to the expiration of the ’295 patent and the ’337 patent. Upon information and belief, Watson is seeking approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of Watson’s ANDA Product prior to the expiration of the ’295 and ’337 patents.

COUNT I
(Infringement of U.S. Patent No. 7,947,295)

29. Alcon incorporates each of the preceding paragraphs 1–28 as if fully set forth herein.

30. Upon information and belief, Watson’s ANDA Product falls within the scope of or is equivalent to a composition falling within the scope of one or more claims of the ’295 patent, including at least claim 10.

31. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson’s ANDA Product would infringe one or more claims of the ’295 patent, including at least claim 10.

32. Upon information and belief, Watson filed as a part of ANDA No. 208816 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the ’295 patent, asserting that the claims of the ’295

patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Watson's ANDA Product.

33. Watson's submission of ANDA No. 208816 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Watson's ANDA Product prior to the expiration of the '295 patent was an act of infringement of the '295 patent under 35 U.S.C. § 271(e)(2)(A).

34. Upon information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product immediately and imminently upon FDA approval of ANDA No. 208816.

35. Upon information and belief, Watson has knowledge of the claims of the '295 patent. Notwithstanding this knowledge, Watson has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product immediately and imminently upon approval of ANDA No. 208816.

36. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '295 patent when ANDA No. 208816 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

37. The foregoing actions by Watson constitute and/or will constitute infringement of the '295 patent and active inducement of infringement of the '295 patent.

38. Upon information and belief, Watson has acted, and will continue to act, with full knowledge of the '295 patent and without a reasonable basis for believing that it would not be liable for infringing the '295 patent and actively inducing infringement of the '295 patent.

39. Alcon will be substantially and irreparably damaged by infringement of the '295 patent. Accordingly, unless Watson is enjoined from infringing the '295 patent and

actively inducing infringement of the ’295 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

40. The Court should declare that the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Watson’s ANDA Product, or any other drug product which is covered by or whose use is covered by the ’295 patent, will infringe and induce the infringement of that patent.

COUNT II
(Infringement of U.S. Patent No. 8,921,337)

41. Alcon incorporates each of the preceding paragraphs 1–40 as if fully set forth herein.

42. Upon information and belief, Watson’s ANDA Product falls within the scope of or is equivalent to a composition falling within the scope of one or more claims of the ’337 patent, including at least claim 1.

43. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson’s ANDA Product would infringe one or more claims of the ’337 patent, including at least claim 1.

44. Upon information and belief, Watson filed as a part of ANDA No. 208816 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the ’337 patent, asserting that the claims of the ’337 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Watson’s ANDA Product.

45. Watson’s submission of ANDA No. 208816 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Watson’s ANDA Product

prior to the expiration of the ’337 patent was an act of infringement of the ’337 patent under 35 U.S.C. § 271(e)(2)(A).

46. Upon information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson’s ANDA Product immediately and imminently upon FDA approval of ANDA No. 208816.

47. Upon information and belief, Watson has knowledge of the claims of the ’337 patent. Notwithstanding this knowledge, Watson has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson’s ANDA Product immediately and imminently upon approval of ANDA No. 208816.

48. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the ’337 patent when ANDA No. 208816 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

49. The foregoing actions by Watson constitute and/or will constitute infringement of the ’337 patent and active inducement of infringement of the ’337 patent.

50. Upon information and belief, Watson has acted, and will continue to act, with full knowledge of the ’337 patent and without a reasonable basis for believing that it would not be liable for infringing the ’337 patent and actively inducing infringement of the ’337 patent.

51. Alcon will be substantially and irreparably damaged by infringement of the ’337 patent. Accordingly, unless Watson is enjoined from infringing the ’337 patent and actively inducing infringement of the ’337 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

52. The Court should declare that the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Watson’s ANDA Product, or any other drug product

which is covered by or whose use is covered by the ’337 patent, will infringe and induce the infringement of that patent.

WHEREFORE, Alcon requests the following relief:

(a) A judgment that Watson has infringed the ’295 patent and will infringe and actively induce infringement of the ’295 patent;

(b) A judgment that Watson has infringed the ’337 patent and will infringe and actively induce infringement of the ’337 patent;

(c) A judgment ordering that the effective date of any FDA approval for Watson to make, use, offer for sale, sell, market, distribute, or import Watson’s ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the ’295 or ’337 patent, be not earlier than the latest of the expiration dates of the ’295 and ’337 patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A preliminary and permanent injunction enjoining Watson, and all persons acting in concert with Watson, from making, using, selling, offering for sale, marketing, distributing, or importing Watson’s ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the ’295 or ’337 patent, or the inducement of any of the foregoing, prior to the latest of the expiration dates of the ’295 and ’337 patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Watson’s ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the ’295 patent, prior to the expiration date of the ’295 patent, will infringe and/or actively induce infringement of the ’295 patent;

(f) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Watson's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '337 patent, prior to the expiration date of the '337 patent, will infringe and/or actively induce infringement of the '337 patent;

(g) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(h) An award of Alcon's costs and expenses in this action; and

(i) Such further and other relief as this Court may deem just and proper.

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